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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------|------------------|
| 10/660,122 | 09/11/2003 | David J. Ecker | DIBIS-0002US.P3 | 7830 |
| 58057 | 7590 | 03/21/2008 | EXAMINER | |
| Casimir Jones, S.C. 440 Science Drive SUITE 203 Madison, WI 53711 | | | BERTAGNA, ANGELA MARIE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/660,122 | ECKER ET AL. | |
| | Examiner | Art Unit | |
| | ANGELA BERTAGNA | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 19 December 2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 30-33 and 50-62 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 30-33 and 50-62 is/are rejected.
 7) Claim(s) 52 and 61 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 11 September 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/19/07; 3/13/08</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on December 19, 2007 has been entered.

Information Disclosure Statement

2. Applicant's submission of an Information Disclosure Statement on December 19, 2007 and on March 13, 2008 is acknowledged. Signed copies are enclosed. It is noted that references 21-25 and 30 on the IDS filed on December 19, 2007 have been lined through. These references should be listed in the NPL section.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Objections

4. Claims 52 and 61 objected to because of the following informalities:

(a) Claim 52 recites "wherein said virus in an immunodeficiency virus". It would appear that "wherein said virus is an immunodeficiency virus" was intended.

(b) Claim 61 recites "2.6-diaminopurine" in line 2. It would appear that "2,6-diaminopurine" was intended.

Appropriate correction is required.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 30-33 and 50-62 are directed to an invention not patentably distinct from claims 14, 18, 23-25, 29, and 30 of commonly assigned US Patent No. 7,217,510 B2. Specifically, claims 14, 29, and 30 of the '510 patent recite a species of the method generically claimed in the instant claim 30. The limitations of the instant claims 32, 53, and 58-61 are recited in claims 25, 30, 14, 18, 23, and 24 of the '510 patent, respectively. The methods recited in the instant claims 31, 33, 50-52, 54-57, and 62 are obvious variants of the methods recited in the '510 patent in view of the prior art of (see sections 7-10 for a more detailed discussion).

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Patent No. 7,217,510 B2, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

7. Claims 30, 32, 53, and 58-61 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14, 18, 23-25, 29, and 30 of U.S. Patent No. 7,217,510 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other, because claims 14, 29, and 30 of the '510 patent recite a species of the method generically claimed in the instant claim 30. Thus, claims 14, 29, and 30 of the '510 patent anticipate the method of the instant claims 30 and 53. The limitations of the instant claims 32 and 58-61 are recited in claims 25, 14, 18, 23, and 24 of the '510 patent, respectively.

8. Claim 31 and 57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14, 18, 23-25, 29, and 30 of U.S. Patent No. 7,217,510 B2 in view of Campbell et al. (Journal of Virological Methods (1996) 57: 175-179; cited previously).

As discussed above the instant claims 30, 32, 53, and 58-61 are an obvious variant of claims 14, 18, 23-25, 29, and 30 of the '510 patent.

The '510 patent does not teach performing the method using multiple primer pairs as required by claim 31 or that the amplification step uses PCR as required by claim 57.

Campbell teaches the use of multiple primers in order to detect every variant (see page 178, column 1). Campbell also teaches PCR amplification (see pages 176-177).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to modify the method of the '510 patent to use multiple primer pairs since Campbell stated, "By using both sets of primers it is highly unlikely that any variant will go undetected (see page 178, column 1)." Thus, an ordinary artisan, concerned with the problem of missing

variants with a mutation in the conserved region of a virus, could resolve this concern by repeating the assay with additional primer sets as taught by Campbell, who teaches that the use of additional primer sets will result in improved detection of all variants. An ordinary artisan also would have been motivated to use any form of amplification known to be useful for amplifying viral nucleic acids, such as the PCR amplification method taught by Campbell, recognizing its suitability for the intended purpose. As noted in MPEP 2144.07, selection of a known process based on its suitability for the intended purpose is *prima facie* obvious in the absence of secondary considerations.

9. Claim 50-52 and 62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14, 18, 23-25, 29, and 30 of U.S. Patent No. 7,217,510 B2 in view of Koster et al. (WO 98/20166; cited previously).

As discussed above the instant claims 30, 32, 53, and 58-61 are an obvious variant of claims 14, 18, 23-25, 29, and 30 of the ‘510 patent.

The ‘510 patent does not teach applying the method to the detection of a respiratory pathogen, hepatitis C virus, or an immunodeficiency virus, as required by claims 50-52, respectively. The ‘510 patent also does not teach incorporating a molecular mass-modifying tag into the amplification product to limit the number of possible base compositions having the mass of the amplification product as required by claim 62.

Koster expressly teaches analysis of respiratory pathogens such as rhinovirus (see page 74, line 1) as well as influenza virus (see page 74, line 8). Koster also teaches analysis of HIV and HCV (see page 73, line 21 and page 74, line 21). Koster also teaches comparison of base

compositions with both modified and unmodified products (see page 66, for example, as well as page 105, Table II and pages 69-70). At page 105, Table II, Koster provides the base composition of three different PCR products determined by MALDI-TOF. Further, Koster specifically discusses using base composition to analyze mutations as discussed on page 70, where Koster notes, "MS can also be used to determine full or partial sequences of larger DNAs; this can be used to detect, locate, and identify new mutations in a given gene region." In particular, Koster expressly teaches the use of MALDI-TOF for diagnosis of bacterial or viral infections (see pages 73-79). Koster exemplifies this analysis in Example 5.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to utilize the viral targets and mass spectrometry method of Koster when practicing the method recited in the claims of the '510 patent, since Koster stated, "In another embodiment, an accurate sequence determination of a relatively large target nucleic acid, can be obtained by generating specifically terminated fragments from the target nucleic acid, determining the mass of each fragment by mass spectrometry and ordering the fragments to determine the sequence of the larger target nucleic acid (see page 75, line 26 to page 76, line 2)."

10. Claim 54-56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14, 18, 23-25, 29, and 30 of U.S. Patent No. 7,217,510 B2 in view of Vanderhallen et al. (Journal of Clinical Microbiology (1998) 36(12): 3463-3467; cited previously).

As discussed above the instant claims 30, 32, 53, and 58-61 are an obvious variant of claims 14, 18, 23-25, 29, and 30 of the '510 patent.

The '510 patent does not teach that the method amplifies a polymerase gene as required by claims 54-56.

Vanderhallen teaches analysis of a polymerase gene for typing EMCV (abstract).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to use the method of the '510 patent to type the clinically relevant EMCV by amplifying a polymerase gene, since Vanderhallen stated, "The PCR technique has increased the sensitivity of detection of viral nucleic acids in clinical specimens (see page 3465, column 2)." An ordinary artisan, interested in improving sensitivity of EMCV detection, would have been motivated to combine the PCR method of Vanderhallen with the mass spectrometric analysis recited in the claims of the '510 patent, in order to identify specific subtypes of viruses that are of clinical significance and permit epidemiological tracking of these viruses.

11. Claims 30, 33, 53, and 59 are directed to an invention not patentably distinct from claims 15, 25, 27, 28, and 37 of commonly assigned US Patent No. 7,255,992 B2. Specifically, claims 15 and 25 of the '992 patent recite a species of the method generically claimed in the instant claim 30. The limitations of the instant claims 33, 53, and 59 are recited in claims 28, 37, and 27 of the '992 patent, respectively.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Patent No. 7,255,992 B2, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly

owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

12. Claims 30, 33, 53, and 59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15, 25, 27, 28, and 37 of U.S. Patent No. 7,225,992 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other, because claims 15 and 25 of the '992 patent recite a species of the method generically claimed in the instant claim 30. Thus, claims 15 and 25 of the '992 patent anticipate the method of the instant claim 30. The limitations of the instant claims 33, 53, and 59 are recited in claims 28, 37, and 27 of the '992 patent, respectively.

Conclusion

13. No claims are currently allowable. It is noted that the claims are free of the art, but they have been rejected for other reasons, specifically obviousness-type double patenting.

Art Unit: 1637

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

amb

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637